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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,590	11/21/2001	Nam Joong Kim	P67297US0	2462

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EXAMINER
DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
1615	9

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/926,590	Applicant(s) KIM ET AL.	
	Examiner Liliana Di Nola-Baron	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Receipt of Applicant's amendment, filed on April 29, 2003, is acknowledged.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 15-18, 21, 22 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,520,927.

The patent provides a slow releasing composition comprising a polypeptide, which is parenterally administered, a tocopherol (vitamin E and vitamin E derivatives) and a release-delaying agent (See col. 2, lines 25-35), and teaches that somatotropin, and in particular recombinant somatotropin, is a suitable polypeptide for the invention (See col. 3, lines 37-45). The patent includes wax among the delaying agents used in the invention (See col. 3, line 64 to col. 4, line 10). The property of being a lubricant is inherent to the wax disclosed in the prior art as delaying agent. Furthermore, the composition disclosed in Example 15 contains Arlacel 165, which is a complex of glyceryl monostearate and PEG-100 stearate, and thus a derivative of PEG and glycerin, as claimed in claim 22 of the instant application. Thus, the patent discloses a composition consisting of somatotropin, a lipid-soluble vitamin and a lubricant, as claimed in claims 15, 16, 18, 21 and 22 of the instant application. With respect to claim 17, in Example 1

the patent provides a composition comprising 100 mg of bovine somatotropin in 1 ml. of tocopheryl acetate, thus the final concentration of somatotropin is 10%. With respect to the amount of lubricant claimed in claim 27, the patent teaches that the amount of delaying agent is 2-10% (See col. 4, lines 18-22), which is in the range of lubricant amount claimed by Applicant. The compositions disclosed by the prior art meet the limitations of claims 15-18, 21 and 27 of the instant application, as they contemplate a composition consisting of somatotropin, vitamin E and lubricant. Thus, the patent anticipates the claimed invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 15-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,497,886.

The patent discloses compositions for injection comprising somatotropin, fat-soluble vitamins, such as vitamin A and vitamin E, solvents, such as ethanol, glycerol, PEGs and benzyl alcohol, and agents to increase the viscosity, such as PEG (See col. 8, line 11 to col. 10, line 34), as claimed in claims 15, 16, 18 and 21-23 of the instant application. With respect to the amounts of the ingredients claimed in claims 17, 19, 20 and 27 of the application, the patent is deficient in

the fact that it does not specify the amounts of each component, however, the patent teaches that the amount of active ingredient per dose unit may vary (See col. 8, lines 17-25) and vitamins can be mixed in any ratio with the active compound of the invention (See col. 9, lines 47-51). Thus, one of ordinary skill in the art would have been able to determine the optimal amount of somatotropin, vitamins and lubricant by routine experimentation. With respect to the limitations of claims 24 and 26, the patent provides injection solutions comprising hydroxybenzoate (See Example 10) and cream formulas comprising PEG-stearate and cetyl palmitate (See Example 12), thus the patent provides esters of a fatty acid and an alcohol. With respect to claim 25, the patent does not specifically include unsaturated fatty acids among the vehicles listed in the disclosure, however, it includes olive oil, which is rich in oleic and linoleic acid.

Thus, the patent discloses compositions comprising somatotropin, vitamins and lubricant. The patent is deficient in the sense, that the compositions of the invention further comprise an additional compound, lactamyl propane, as solvent for active ingredients in the composition (See col. 8, lines 11-16), thus the compositions of the prior art are not consisting only of somatotropin, vitamin and lubricant, as claimed by Applicant. The burden is shifted to Applicant to show that the presence of the additional compound would be detrimental to the composition as claimed.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of the patent to device compositions consisting of somatotropin, vitamins and lubricants to obtain somatotropin compositions. The expected result would have been a successful injectable composition comprising somatotropin. Because of the

teachings of the patent, that vitamins can be mixed in any ratio with the active compound and the composition may comprise a lubricant, one of ordinary skill in the art would have a reasonable expectation that the compositions claimed in the instant application would be successful. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

5. Applicant's arguments filed on April 29, 2003 have been fully considered but they have been found only partially persuasive.

6. Applicant's argument with respect to the obviousness-type double patenting rejection of claims 1-8, 11 and 14 of the previous Office action have been found persuasive, since the prior art does not specifically teach that lecithin acts as lubricant. Accordingly, said rejection is withdrawn.

7. Applicant's amendment has overcome the 35 U.S.C. 112, second paragraph rejection of claims 8-13 of the previous Office action. Accordingly, said rejection is withdrawn.

8. Applicant argues that the object of U.S. Patent 5,520,927 to Kim et al. is different from the object of the instant application and the vitamins in the composition have a different purpose from the purpose of the prior art. In response to said argument, it is noted that Applicant's invention is directed to compositions, and feature intended use has no patentable weight in composition claims. The art discloses compositions comprising the same ingredients as those claimed by Applicant, regardless of the purpose of each ingredient in the composition.

9. In response to Applicant's argument, that phosphatidylcholine is not a lubricant, it is noted that the patent includes wax among the delaying agents used in the invention (See col. 3, line 64 to col. 4, line 10). Wax is a natural lubricant and the property of being a lubricant is inherent to the wax disclosed in the prior art as delaying agent. Furthermore, the composition disclosed in Example 15 contains Arlacel 165, which is a complex of glyceryl monostearate and PEG-100 stearate, a derivative of PEG and glycerin, which is claimed as lubricant by Applicant.

10. The 35 U.S.C. 102(e) rejection of claims 1-8, 11 and 14 of the previous Office action is withdrawn in view of Applicant's statement, that the invention published in WO 99/43342 was derived from the inventors of the instant application.

11. In response to Applicant's argument, that Breitenbach et al. discloses a composition comprising a solvent, and the composition claimed by Applicant does not include said solvent, the burden is shifted to Applicant to show that the presence of the additional compound would be detrimental to the composition as claimed.

Conclusion

12. Claims 15-27 are rejected.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

June 9, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600